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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hong Jin

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EXAMINER

LUCAS, ZACHARIAH

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/724,416	<b>Applicant(s)</b> JIN ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 49,53,57,69,70,73 and 83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49,53,57,69,70,73 and 83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Currently, claims 49, 53, 57, 69, 70, 73, and 83 are pending and under consideration.
2. In the prior action, the Final action mailed on April 30, 2008, claims 49, 53, 57, 69, 70, 73, and 83 were pending and rejected.
3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 30, 2008 has been entered.

In the submission, Applicant amended claims 49, 57, and 73.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on July 30, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. **(Prior Rejection- Maintained)** Claims 49, 57, 70, and 73 were rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al. (U.S. Patent 5,993,824- of record in the action mailed on June 5, 2002). The claims have been amended such that they now require a deletion within, rather than of, the NS1 gene. I.e., the claims now read on embodiments comprising deletions of one or more nucleotides within the NS1 gene and no longer require the deletion of the gene in its entirety.

Applicant traverses the rejection on the basis that the parent application 08/316439 (now U.S. Patent 5,840,520) provides specific descriptive support for the claimed invention. In particular, Applicant asserts that support for a genus of recombinant RSV comprising deletions within the NS1 gene may be found in the teachings of the patent application suggesting any deletion within the RSV genome, and that because the application teaches the deletion of the influenza NS1 protein, suggests that the alterations to the influenza virus may be carried over to RSV, and because the NS1 protein of RSV was known. Applicant appears to suggest that because an application need not disclose that which is conventional or well known in the art, the

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fact that the application did not specifically refer to the RSV NS1 gene is not important. The arguments are not found persuasive.

As with the previous limitation referred to a deletion of the NS1 gene, the parent application lacks any specific support for deletions with the NS1 gene in particular. There is nothing in the parent application to specifically direct those in the art to making such deletions. Applicant's reference to the teachings of the parent application with respect to the NS1 protein of influenza is noted. However, such teachings are not found adequate for substantially the same reasons as indicated on pages 4-5 of the prior action.

Moreover, in view of the lack of knowledge in the art as to the function of the NS1 protein, it is not clear that those in the art would have considered that the parent application provides adequate support for recombinant and attenuated (implying at least some residual ability to infect, and replicate in, cells) RSV particles comprising any deletion of the NS1 gene in part or in full. I.e., the teachings of the art and application were inadequate to provide descriptive support for deletions in the NS1 gene that would result in an RSV viral particle comprising the functions required by the present claims.

In addition, while the Applicant may rely on conventional or well-known information in the art for support for a claimed invention, such does not permit the Applicant to import such information into an application to create new limitations in the claimed subject matter which are not otherwise disclosed in the application. The legal citations provided by the Applicant do not appear to specifically address this issue. In contrast, the issue was examined in the Federal Circuit court's decision in the case of Lockwood v. American Airlines Inc., 41 U.S.P.Q.2d 1961 (1997). In this case, one of the parties argued, as is done by the present Appellant, that, in

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determining if there is written description support for a claim limitation in an application, it is an error to look "solely at the applications themselves." *Id.*, at 1966. This argument was not found persuasive by the court. Rather, the court stated as follows: "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed."

For these reasons, and for the reasons of record, the amendments to the claims and arguments pursuant thereto are not found sufficient to overcome the rejection. The rejection is therefore maintained.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 49, 53, 57, 69, 70, 73, and 83 were rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy as applied above, and further in view of the teachings of Knipe et al. (U.S. 7,223,411) and Inglis et al. (U.S. 5,665,362). Applicant traverses the rejection on the same basis asserted with respect to the rejection over Murphy above. For the reasons indicated above, the argument is not found persuasive and the rejection is maintained.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Double Patenting***

10. **(Prior Rejection- Withdrawn)** Claim 49 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 24 of copending Application No. 11/690,957. In view of the amendments to the copending claims, the rejection is withdrawn.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. **(Prior Rejection- Restated and Maintained)** Claims 57, 70, and 73 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable

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over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957. In view of the amendment of the copending claims, the rejection is extended to claim 49.

Applicant traverses the rejection on the grounds that the copending claims of the '957 application have been cancelled. The argument is not found persuasive in view of the submission of new claims 36, 40, 47, and 54 in the copending application. While the copending claims do not specify the presence of a polymerase binding site of an RSV in the infectious RSV described therein, the claims do require that the RSV of those claims is infectious and attenuated (retaining the ability to replicate). Thus, the claims implicitly require the presence of those viral sequences required for such activity, such as the viral polymerase binding site. The present claims therefore represent obvious embodiments of the copending claims. The rejection is therefore maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. **(Prior Rejection- Maintained)** Claims 53, 69, 71, and 83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of copending Application No. 11/690,957 in view of Murphy (supra), Knipe (supra.), and Inglis (supra). The Applicant traverses this rejection on the basis asserted with respect to the rejection of claims 57, 70, and 73 for obviousness-type double patenting over the claims of the copending application above. The rejection is restated as a rejection of the claims over claims 36, 40, 47, and 54 of copending Application No. 11/690,957 in view of Murphy (supra), Knipe (supra.), and Inglis (supra). Applicant's arguments are not found persuasive for the reasons indicated with respect to the double patenting rejection of claims 57,



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70, and 73 above. Further, the rejection is further maintained in view of the application of the Murphy reference as prior art for the reasons indicated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648